Briumvi™ (ublituximab-xiiy) – New drug approval

- On December 28, 2022, TG Therapeutics announced the FDA approval of Briumvi (ublituximab-xiiy), for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

- The efficacy of Briumvi was established in two randomized, double-blind, double-dummy, parallel group, active comparator-controlled clinical studies (study 1 and study 2) in 1,094 patients with RMS treated for 96 weeks. Patients received Briumvi + oral placebo or Aubagio® (teriflunomide) + intravenous (IV) placebo. The primary outcome of both study 1 and study 2 was the annualized relapse rate (ARR) over the treatment period.

    - In study 1, the ARR was 0.076 in the Briumvi-treated patients vs. 0.188 in the Aubagio-treated patients (relative reduction 59%; $p < 0.001$).
    - In study 2, the ARR was 0.091 in the Briumvi-treated patients vs. 0.178 in the Aubagio-treated patients (relative reduction 49%; $p = 0.002$).

- Briumvi is contraindicated in patients with active hepatitis B virus infection and a history of life-threatening infusion reaction to Briumvi.

- Warnings and precautions for Briumvi include infusion reactions, infections, fetal risk, and reduction in immunoglobulins.

- The most common adverse reactions (≥ 10%) with Briumvi use were infusion reactions and upper respiratory tract infections.

- The recommended dose of Briumvi should be administered under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage severe reactions, such as serious infusion reactions. The dosage schedule is as follows:

    - First infusion: 150 mg IV infusion
    - Second infusion: 450 mg IV infusion administered two weeks after the first infusion
    - Subsequent infusions: 450 mg IV infusion administered 24 weeks after the first infusion and every 24 weeks thereafter.
    - In addition, patients should be pre-medicated with 100 mg of methylprednisolone administered IV (or an equivalent oral dosage or equivalent corticosteroid) approximately 30 minutes prior to each Briumvi infusion to reduce the frequency and severity of infusion reactions and an antihistamine (eg, diphenhydramine) administered orally or IV approximately 30-60 minutes prior to each Briumvi infusion to further reduce the frequency and severity of infusion reactions. The addition of an antipyretic (eg, acetaminophen) may also be considered.
    - Consult the Briumvi drug label for additional dosing information.

- TG Therapeutics plans to launch Briumvi in 1Q2023. Briumvi will be available as a 150 mg/6 mL preservative-free solution in a single-dose vial.